UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA	)	
	)	
Plaintiff,	)	Civil Action No. 99-CV-2496 (GK)
	)	
v.	)	Next scheduled appearance:
	)	Trial (ongoing)
PHILIP MORRIS USA INC.	)	
(f/k/a Philip Morris Incorporated), *et al.*	)	
	)	
Defendants.		

WRITTEN DIRECT EXAMINATION OF SCOTT APPLETON, Ph.D.
SUBMITTED BY THE JOINT DEFENDANTS PURSUANT TO ORDER #471

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I. BACKGROUND

Q. Please state your name.

A. Scott Appleton.

Q. By whom are you currently employed?

A. Philip Morris USA.

Q. Prior to working at Philip Morris USA, where did you work?

A. I worked at Brown & Williamson Tobacco Corporation from 1991 until 2004. I also worked at R.J. Reynolds from approximately 1985 through 1989.

Q. What was your position with Brown & Williamson during that time?

A. For the majority of the time that I was with Brown & Williamson, I was Director of Scientific and Regulatory Affairs.

Q. Who represents you in connection with your appearance here today?

A. Mr. Bernick and his colleagues at Kirkland & Ellis.

Q. Is your testimony here today limited to matters that occurred while you were employed by Brown & Williamson?

A. Yes.

Q. Before we get into detail about your work for Brown & Williamson, please describe your educational background?

A. I received a Bachelors Degree in Human Nutrition and Food Science from the State University of New York College at Buffalo. I earned a Masters Degree in Nutrition with a minor in Toxicology from Iowa State University, and my Ph.D. is in Environmental Toxicology with minors in Nutrition and Pathology from Cornell University in Ithaca, NY.

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Q. Have you met the requirements to become and remain Board Certified in toxicology by the American Board of Toxicology?

A. Yes.

Q. Are you involved in other toxicology and professional organizations?

A. Yes. Among other things, I am a member of the Society of Toxicology. I have given invited presentations and reviews in the field of toxicology, and I was a member of the safety evaluation and coordination committee of the Flavor and Extracts Manufacturers Association. I have over 35 presentations and publications in toxicology related areas.

Q. Tell us briefly, what is toxicology?

A. Toxicology is the study of harmful effects of chemical substances on living beings, including trying ultimately to understand the effects on humans.

Q. Have you been employed as a toxicologist in positions outside of the tobacco industry?

A. Yes, at different times during my career, I have held positions as a civilian employee of the US Army doing toxicological evaluations of antidotes for chemical warfare agents, and as an employee of Best Foods doing health and safety assessments of ingredients, environmental health and safety assessments and cancer research. After working at R.J. Reynolds in the late 1980s, I left to become manager of the Regulatory Affairs Department of the flavor ingredients company Fries & Fries.

Q. You have mentioned that you worked in "regulatory affairs" for Brown & Williamson and other companies. Will you tell us what that is?

A. The responsibilities of regulatory affairs varies by company, depending on the products the company is making, but basically it means responding to regulatory requirements. That is,

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making sure you are complying with whatever regulatory requirements there are for selling your products in a particular country, dealing with health and safety issues in many cases.

Q. When did you go to work for Brown & Williamson?

A. In 1991.

Q. What were your principal responsibilities at Brown & Williamson?

A. I evaluated both the regulatory status and the health effects of new ingredients and new materials, including assessing new ingredients and cigarette construction materials for acceptability from a toxicological perspective. I was responsible for monitoring the scientific literature pertaining to smoking and health and maintaining expertise in the area of smoking and health. I was also hired to assist with regulatory submissions to various bodies and assist the lawyers in preparing for litigation. Finally, I was informed that I might be asked to testify or assist others in preparing testimony on behalf of the company in smoking and health litigation.

Q. Let's talk a little bit about your compensation at Brown & Williamson. What was your salary.

A. I don't recall exactly what it was at all times, but my base was approximately $170,000 a year. I would, on occasion, receive a bonus in the neighborhood of $50,000. I was also part of a profit sharing plan, and I had other benefits that included insurance, stock options in Brown & Williamson's ultimate parent corporation, and I am receiving a pension.

Q. Was your compensation ever tied to your testimony in smoking and health cases?

A. No. I was never paid extra for my time and any testimony I gave was not considered during my performance evaluation.

Q. What is your current compensation at Philip Morris USA?

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A. It is about $175,000 base. I am also eligible for a bonus and a profits sharing plan in two years.

Q. Is your compensation at Philip Morris USA in any way dependent on your appearance to testify here today?

A. No.

Q. During your work at Brown & Williamson, did you become familiar with the kinds of research that had been done by Brown & Williamson?

A. Yes, I did. I reviewed documents in the Brown & Williamson library, as well as ones sent to me by other people. I spent a fair amount of time talking to people who did research, and during my tenure at the company, I was intimately involved with ongoing research that the company conducted.

Q. Was there a time during your work at Brown & Williamson that you reported to Dr. Jeffrey Wigand?

A. Yes, my first few months at Brown & Williamson I was on a self-directed work program. After that, Dr. Wigand became my supervisor. I reported to him until he left the company in 1993.

Q. For purposes of taking your testimony in this case, I am going to focus your attention and have you respond to a series of specific claims that have been made by Government witnesses about Brown & Williamson.

A. Okay.

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II. COUMARIN

Q. Let me start by directing your attention to certain claims that have been made by Dr. Wigand. First, during Dr. Wigand's testimony in this case, he was asked about when he testified as follows:

> "Question: At any time did you learn that Brown & Williamson was using a form of rat poison in pipe tobacco?
>
> Answer: Yes.
>
> Question: What form of rat poison is that?
>
> Answer: It's a compound called coumarin. It was contained in pipe tobacco."

(1/31/05 Wigand Trial Testimony at p. 11578, quoting 11/95 Dep., *Estate of Butler v. Philip Morris* at 71).

Are you familiar with that testimony?

A. Yes.

Q. Dr. Appleton, was it your understanding as a scientist at Brown & Williamson that coumarin is a rat poison?

A. No. Coumarin is not a rat poison. It is a fragrance ingredient that occurs naturally in a lot of things, including cut hay, sweet clover, strawberries and cinnamon. It has been used as a fragrance material in a variety of consumer goods, including pipe tobacco.

Q. Is the claim that coumarin is a rat poison false?

A. Yes.

Q. In this case, Dr. Wigand testified that his earlier testimony about coumarin had not been false because what he meant was that coumarin "is a precursor to what's called a rodencide [sic], dicoumarol, and Coumadin." Wigand Trial Testimony at 11578

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(1/31/2005). Is it accurate to say that Brown & Williamson knew that coumarin was a "form" of rat poison?

A. No. We were well aware in the company that the toxicological properties of a particular chemical may change dramatically as the structure of the chemical is modified to form new compounds. Just because two compounds are chemically related, that does not necessarily mean they have similar biological properties. An example is the distinction between nicotinic acid, which is also known as niacin or vitamin B_3, and nicotine. Nicotinic acid is a breakdown product of nicotine and, therefore, chemically related to nicotine. Despite being chemically related, nicotinic acid is not a "form" of nicotine and has very different biological properties from nicotine. Nicotinic acid is an essential nutrient while nicotine is classified by the U.S. Surgeon General as an addictive drug. Therefore, it would not be correct to say that nicotinic acid (vitamin B_3) is a "form" of nicotine.

Similarly, we knew that coumarin is chemically related to Coumadin (also known as warfarin). However, like the example of nicotinic acid and nicotine, their biological properties are very different. Coumadin has anticoagulant activity (inhibits blood clotting) which makes it useful as a rat poison. Coumarin does not. Therefore, it would be misleading to say that use of coumarin as a fragrance material was using a form of rat poison.

III. ACETALDEHYDE

Q. Let's turn to the subject of acetaldehyde. In his written direct testimony in this case, at page 119, Dr. Wigand testified that "[a]cetaldehyde is an impact booster that augments the effect of nicotine," and that "acetaldehyde enhances the synergistic effect of nicotine and the physiological effect." He claims that "Brown & Williamson was aware of additives that were derived from simple sugars that when burned produced acetaldehyde.

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Brown & Williamson purposely added these simple sugar derivatives to cigarette casings, knowing that when burned the additives would result in the production of acetaldehyde which would be inhaled by the smoker."

Dr. Appleton, let me start by asking whether Brown & Williamson ever directly added acetaldehyde to its cigarettes?

A. No. It was present as a minor component in some complex flavor mixtures purchased from flavor companies. These mixtures were used in the manufacturing of cigarettes.

Q. How did acetaldehyde come to be in flavorings used in Brown & Williamson cigarettes?

A. At Brown & Williamson, we understood that acetaldehyde occurs naturally in many foods, particularly fruits, and it had also been approved by the FDA as an ingredient to add directly to food. Flavoring companies with whom we dealt prepared flavors that consisted of complex mixtures and that could contain acetaldehyde. From my experience in dealing with flavoring companies, I understood that acetaldehyde was usually added to give flavor mixtures a pleasant aroma upon opening a sample bottle. Brown & Williamson purchased flavorings from other companies, and when it did so, it purchased the mixtures prepared by the flavor company. For a time, Brown & Williamson purchased some flavor ingredients that did contain acetaldehyde in very small amounts.

Q. Was there any toxicological significance to that whatsoever, from your view at Brown & Williamson?

A. None whatsoever. Even if acetaldehyde was used in flavoring ingredients, because it is extremely volatile, it will evaporate at room temperature. By the time it reached the market, Brown & Williamson expected that little, if any, was in the cigarette. Moreover, it occurred in

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commercial mixtures at extremely low levels that are dwarfed by naturally occurring levels of acetaldehyde in smoke that result from burning tobacco.

Q. Did the acetaldehyde from the commercial flavor mixtures increase the levels of acetaldehyde that naturally occur in smoke?

A. It is highly unlikely because of its minute levels and extreme volatility.

Q. Did it have anything to do with enhancing nicotine effects?

A. No. We included acetaldehyde only because it was already included in prepared flavor mixtures. We were not specifically adding acetaldehyde. It was just "along for the ride," so to speak, as a component in commercial flavor mixtures in the manufacturing process.

Q. Are you aware of allegations Dr. Wigand has made in past testimony that acetaldehyde is knowingly added to cigarettes to enhance the effects of nicotine?

A. Yes. However, there would be no reason for a cigarette company to add acetaldehyde to cigarettes because it is so volatile that it would evaporate within minutes of its addition to tobacco and therefore little, if any, would be present in the finished product by the time it reached the marketplace.

Q. Now, what about Dr. Wigand's contention, made in this case, that Brown & Williamson adds sugars to tobacco for the purpose of facilitating the production of acetaldehyde in smoke -- did that happen?

A. No. Most manufacturers have for decades added sugars to some blends of tobacco to make the smoke smoother and milder. Brown & Williamson has done likewise, but it was never done to cause the production of acetaldehyde gas in smoke.

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Q. Has Brown & Williamson been aware of research that examines the relationship between the sugar content of the tobacco blend and the acetaldehyde content in tobacco smoke?

A. Yes, there are several types of research that I was aware of when I worked at Brown & Williamson.

Q. Will you describe the types of research?

A. Yes. One category of studies we reviewed were ones that examine the sugar content of commercial cigarettes as well as acetaldehyde content of those cigarettes when smoked to determine the correlation, if any, between blend sugar content and smoke acetaldehyde levels. Such studies have shown no correlation between blend sugar content and smoke acetaldehyde levels, even across a wide range of sugar contents.

Q. Please look at Exhibit JD-011165, an article by scientists from Imperial Tobacco Limited. Is this one of the articles you were aware of that has been published on the effect of natural sugar content of tobacco upon acetaldehyde concentrations found in cigarette smoke?

A. Yes, it is a 1975 article that is right on point.

Q. What is the conclusion reached in the study?

A. The conclusion, at p. 9, reads, "All of the evidence obtained in our laboratories has shown that the total aldehyde yield in tobacco smoke is not related to either sugar content or the equilibrium moisture content of the tobacco."

Q. Is there a second type of study regarding sugar and acetaldehyde in smoke?

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A. Yes. The second type of studies we were aware of -- and some of which were conducted by the industry -- added sugar to a blend to determine the effect, if any, on acetaldehyde levels in smoke.

Q. Turning to Exhibit JD-011164. Is this an article dealing with that subject?

A. Yes.

Q. Who authored this study?

A. It was written by Ray Thornton and S. R. Massey, BATCo scientists with the Group Research and Development Centre in Southampton.

Q. What did the study show with respect to the effect of adding more sugar?

A. The BATCo scientists started with Burley tobacco, which has a very low natural level of sugar. They then added different types of sugar at levels that are much higher than you would normally use. The study shows virtually no change in the delivery of acetaldehyde in smoke as a result of the addition of various levels of sugar.

Q. Is that what you would expected from your experience in working in the industry?

A. Yes. I understood that many materials create acetaldehyde naturally when burned, including both tobacco and sugar. Since tobacco produces more acetaldehyde than sugars, the replacement of some tobacco in a cigarette with sugar would, if anything, be expected to reduce the formation of acetaldehyde.

Q. Were you aware of other studies that bear on the relevance of acetaldehyde in cigarettes?

A. Yes. A last area of research of which we were aware looked at whether acetaldehyde levels in cigarettes have any effect on acetaldehyde levels in the blood of people.

Q. What did you learn from those studies?

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A. Studies comparing acetaldehyde in the blood of non-smokers compared to smokers show no difference in acetaldehyde levels in the blood.

Q. Is there any truth to the claim that Brown & Williamson introduced acetaldehyde into cigarette smoke by adding sugar, in order to enhance nicotine effects?

A. No.

IV. AMMONIA

Q. Now let's turn to claims about the reasons for using ammonia in cigarettes. In his testimony for the Government in this case, Dr. Wigand made a number of claims concerning Brown & Williamson's use of ammonia in its products. I'd like to break those claims down and deal with them individually, beginning with his claims relating to ammonia and pH.

A. All right.

Q. At page 117 of his written direct testimony, Dr. Wigand has testified that "[i]t was believed at Brown & Williamson that by using ammonia you changed the pH of the smoke. ... The change in pH was understood to create more free nicotine in the smoke phase. This made more of the nicotine in the cigarette available to the smoker more rapidly. This more rapid transfer of nicotine was thought to increase the pharmacological impact of the cigarette and thus made the smoking sensation more enjoyable for the smoker."

First, Dr. Appleton, while you were at Brown & Williamson, did you understand that it was some kind of secret that if the pH in cigarette smoke goes up, then the amount of free form nicotine starts to rise?

A. No, that information had been known for some time, and was published in well-known and widely read publications.

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Q. Please look at Exhibit JD-040395 and identify it for the Court?

A. It is a research note by G. Morie, of the Tennessee Eastman Company, entitled "Fraction of Protonated and Unprotonated Nicotine in Tobacco Smoke at Various pH Values" which was published in the journal Tobacco Science in 1972.

Q. What did this article show with respect to pH and nicotine levels?

A. There is a chart demonstrating the precise issue we have been talking about. It shows that, in theory, as pH increases, free nicotine also starts to rise, particularly after you get above a pH of 6.5. So, scientists and others were aware of the issue from the published literature.

Q. Please look at U.S. Ex. 64,071, which is the 1979 Surgeon General's Report. Were you aware of whether the Surgeon General had also discussed this issue?

A. Yes. The Surgeon General pointed out the same relationship between the pH of smoke and free and bound nicotine at pages 14-85 and 14-86 of the 1979 Report.

Q. Is the chart identified on the aforementioned pages of the 1979 Report the same or different from the chart in the Morie article?

A. It is substantially the same.

Q. Now lets turn to the question of whether ammonia actually affects the pH of commercial cigarettes.

Dr. Benowitz and Dr. Henningfield both testified that they did not know whether the addition of ammonia in actual commercial brands made the pH of smoke go up. Dr. Benowitz testified: "But I have no personal experience with this. I don't know how much ammonia is added. I don't know how much pH is affected. I really do not know any details of ammonia and the tobacco manufacturing process and the impact on pH." (11/02/04 Trial Testimony at 4790). Dr. Henningfield likewise testified that "[m]y

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conclusion is that there are serious unanswered questions and I do not know what the specific role of ammonia compounds is in any given cigarette on the market." (11/29/04 Trial Testimony at 7167).

Is the question of pH levels in commercial cigarette smoke one that you looked at when you were at Brown & Williamson?

A. Yes.

Q. As an initial matter, did Brown & Williamson add ammonia to some of its cigarette brands?

A. Yes.

Q. In what ways was ammonia used in cigarettes?

A. Ammonia was used in making some of Brown & Williamson's reconstituted tobaccos, such as CPCL, which in turn were used in varying amounts in the company's cigarettes. Ammoniated recon was used in different ways to achieve different taste characteristics. Ammonia was not used in all brands and was initially not used in menthol cigarettes because some people felt that the taste characteristics produced by use of ammonia were not compatible with menthol.

Q. Did Brown & Williamson investigate whether the use of ammonia increased the pH of tobacco smoke?

A. Yes.

Q. Please look at Exhibit JD-010429 and describe that document for us?

A. It is a report done by R.F. Shehadeh at Brown & Williamson entitled "Part I: Effect of Reconstituted Tobacco on Cigarette Smoke Properties," dated August 26, 1996.

Q. What were the scientists looking at in this report?

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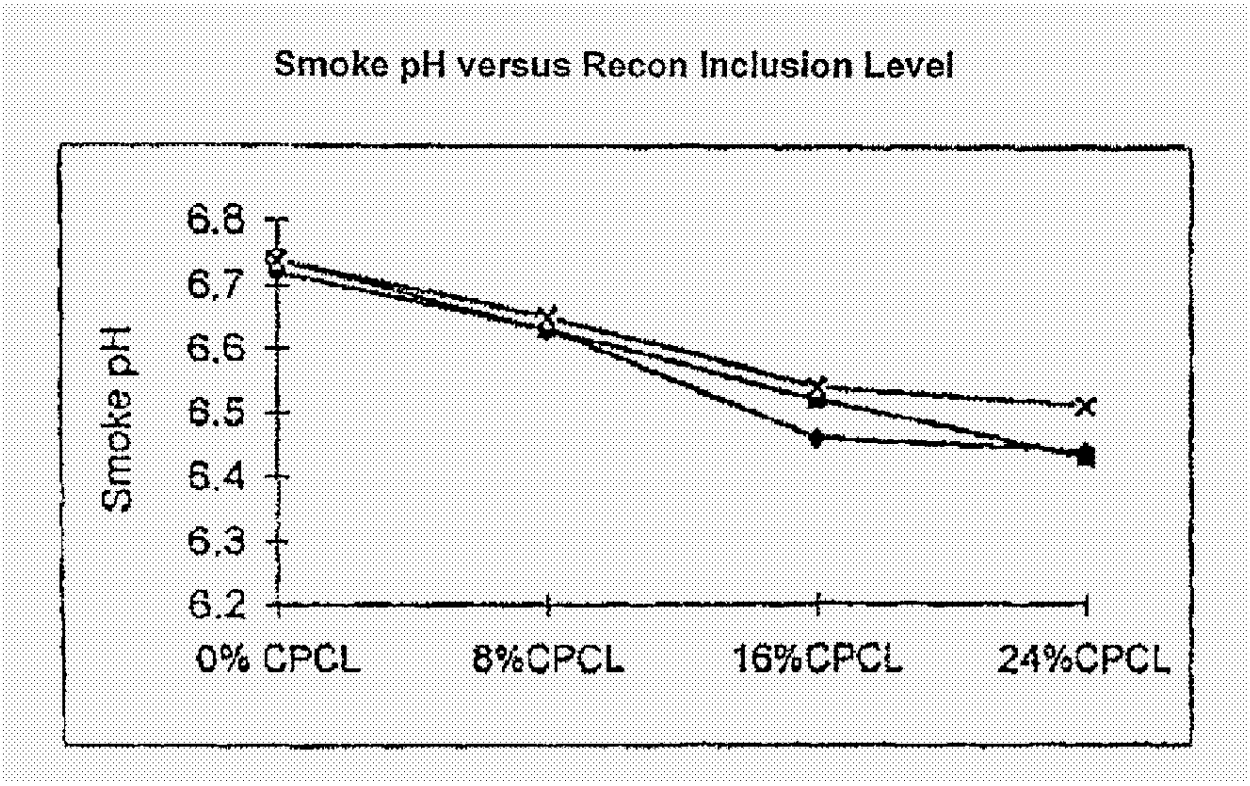
A. They were looking at four reconstituted tobacco products, one of which included CPCL. CPCL contained diammonium phosphate, a form of ammonia.

Q. What was the conclusion with regard to pH?

A. The conclusion, on page 6, was, "Since the decrease was observed for all four recons, with . . . and without . . . sugar-ammonia chemistry, incorporating sugar-ammonia chemistry in recons does not seem to have an effect on altering the smoke pH of a cigarette."

Q. If we actually turn to the charts, as you understand the data, did they show what happens to smoke pH as you increase the amount of recon?

A. If you look at Figure 8 on page 16, part of which is reproduced here, it shows that as you increase CPCL from 0 percent up through 8, 16 and 24 percent, you have a slight reduction in smoke pH.



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Q. Did this Brown & Williamson report provide any support for the notion that by adding an ammonia-treated reconstituted tobacco to the blend, you are increasing pH and manipulating nicotine?

A. No. It showed that the ammonia-treated reconstituted tobacco used by Brown & Williamson did not have any significant effect on smoke pH.

Q. Let's talk about how much smoke pH has to go up before you really start to have free nicotine. When you were at Brown & Williamson, were you aware of any guidance provided by the Surgeon General on how high the smoke pH has to go before you start to get significant amounts of free nicotine?

A. Yes, in the 1979 Surgeon General's Report.

Q. What does the Surgeon General say on that subject?

A. On page 14-108, he states that, "Since the cigarettes in the United States and in most foreign countries are made of flue-cured tobacco, are blends with flue-cured tobacco as a major ingredient or, in a few cases, are blends with Turkish tobacco, the pH of the resulting mainstream smoke is below 6.5 and thus essentially contains only protonated nicotine."

Q. The Surgeon General uses the term "protonated". Does that mean that the nicotine is bound or free nicotine?

A. Protonated means bound nicotine.

Q. So what was your understanding at the company of what the Surgeon General was saying with respect to the pH in cigarettes?

A. He was saying that the pH of smoke from U.S. commercial cigarettes is below 6.5 pH and thus essentially contains only protonated nicotine, not free nicotine.

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Q. And what did Shehadeh indicate about the amount the pH of smoke from Brown & Williamson brands?

A. The Shehadeh study showed that the pH of Brown & Williamson tobacco was below the level at which, according to the Surgeon General and others, free nicotine would form. So, we understood that essentially all of the nicotine in smoke from Brown & Williamson brands was in the bound state.

Q. If ammonia was added to increase pH, what would you, at Brown &Williamson, have expected to have seen over time with respect to the pH of smoke?

A. If addition of ammonia to cigarettes truly increased smoke pH, you would expect the pH to be higher.

Q. Please look at Exhibit JD-041895 and identify it for the Court?

A. It is a 1997 report prepared by W.S. Rickert for the Massachusetts Department of Health, entitled "Partial Characterization of 10 'Common' Brands of American Cigarettes."

Q. What was your understanding at Brown & Williamson of the results of this study with respect to the pH of the smoke from commercial cigarettes?

A. Table 2 on page 12 shows the pH of smoke from many commercial cigarettes, including the Brown & Williamson Carlton brands. The study confirmed our understanding that all of the cigarettes were below a pH of 6.5, and within a range from 5.99 to 6.35.

Q. Please look at JD-010892, and identify it.

A. It is a 1967 article by scientists at R.J. Reynolds, A. Sensabaugh and R.H. Cundiff, entitled "A New Technique for the Determination of the pH of Whole Tobacco Smoke," which was published in Tobacco Science.

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Q. Looking back to 1967 in this article, what did these industry authors demonstrate with respect to the pH of smoke from domestic blend cigarettes at that time?

A. The pH range for 85 mm blended cigarettes with a conventional cellulose acetate filter, which is most representative of cigarettes on the market today, ranged up to 6.14.

Q. Then, if we look at the Morie article from 1972, Exhibit JD-040395, what was your understanding of Morie's statements regarding the highest pH levels of smoke from US cigarettes?

A. According to Morie, the pH ranges up to 6.2.

Q. Were you aware of other researchers who reached similar findings in the 1970s?

A. Yes. In 1973, K.D. Brunnemann and D. Hoffman published a study entitled "The pH of Tobacco Smoke." (Exhibit JD-000735). They researched the pH of the smoke of various tobacco products.

Q. What was your understanding of their findings?

A. They plotted their data regarding the pH of mainstream smoke of various tobacco products on Chart 5, on page 118 of their article. Based on the data shown in the chart, they concluded on page 122 that "Cigarettes made from Bright tobacco or blended tobacco deliver mainstream smoke below a pH of 6.2 and consequently contain only small amounts of unprotonated nicotine."

Q. What type of cigarettes are sold in the United States and by Brown & Williamson?

A. The blended type examined by Brunnemann.

Q. During the approximately 25 years between the Sensabaugh, Morie and Brunnemann studies and the Rickert study, did you believe that there had been any significant change in the pH of smoke from commercial cigarettes?

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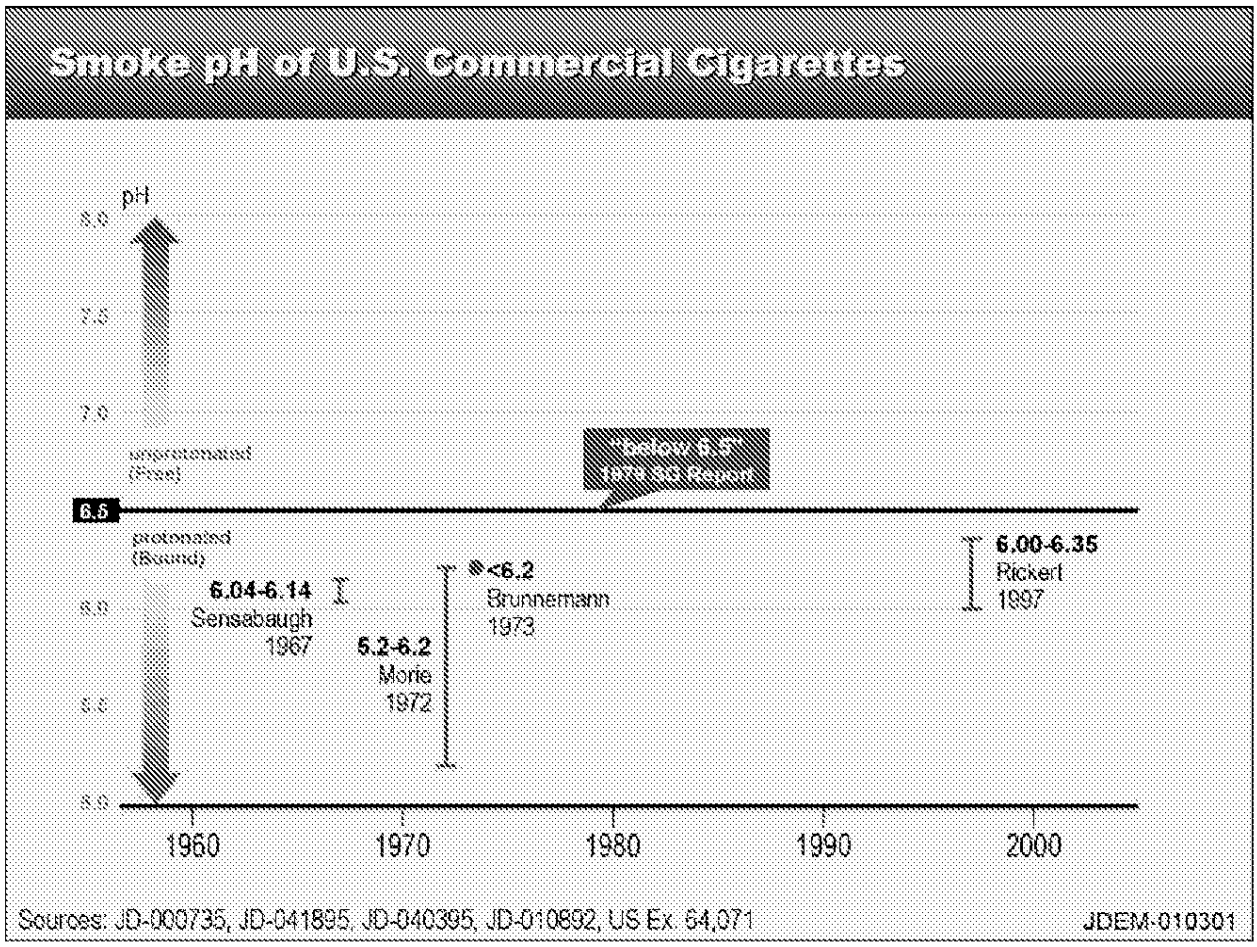
A. No. If you look at Exhibit JDEM-010301, it shows studies of the pH of commercial cigarettes in the United States over time. There has been no significant change.



Q. Is it your understanding that there were any Brown & Williamson cigarettes being tested across this period of 25 years that get to the level that the Surgeon General says will give you something other than essentially protonated nicotine?

A. No.

Q. Were any of the cigarettes in the range where you have significant free nicotine?

A. No.

Q. Were you aware at Brown and Williamson of whether there are variations in pH that are a natural consequence of using different types of tobacco in a cigarette?

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A. Yes. The two major types of tobacco are flue-cured, which tends to yield smoke with a lower pH, and Burley tobacco, which tends to yield smoke with a higher pH than flue-cured. So, as you produce different blends, pH levels in smoke will vary somewhat naturally as a result of different proportions of tobaccos used in the blend.

Q. Since we know that Brown & Williamson did use ammonia in some of its products, for what purpose did the company use ammonia?

A. Brown & Williamson used ammonia to improve the taste and sensory properties of its cigarettes. When sugar reacts with ammonia, which is what happens in a burning cigarette, it undergoes a reaction that is well-known in the food chemistry literature, called the Mailard reaction. The reaction is what gives baked foods such as bread dough, meat, nuts or coffee, a "roasty" type of aroma or flavor. We have discovered that when you add those types of components to tobacco, you can generate a roasted or toasted flavor or aroma that people find pleasant.

Q. Does the reaction occur with blended tobaccos even if you don't have ammonia?

A. Yes. It does occur naturally with the sugar and ammonia which occur naturally in tobacco. If you add sugar and ammonia, you can enhance the reaction.

Q. Is the use of ammonia to improve taste discussed in Brown & Williamson documents?

A. Yes. Among other documents, it is discussed in U.S. Ex. 86,908, which is the Leaf Blender's Manual, or Root Technology Handbook. On page 1, it discusses "What Ammonia Does," and states that "ammonia in tobacco reacts with reducing sugars to form non-volatile flavor precursors." At page 12, it also notes that CPCL "increases Burley character in the blend,

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while reducing irritation." Burley character is the chocolaty, rich, roasted character of the smoke from Burley tobacco.

Q. The Leaf Blender's Handbook also talks about ammonia affecting "impact." Dr. Wigand says that the term impact, as used in Brown & Williamson documents, means "nicotine rush." Is that true?

A. No. Impact is a term that describes one of the many sensory characteristics of smoke. It is used by product developers at the company to have people characterize cigarettes that are being tested. There are various terms used to characterize cigarettes, such as taste and strength. The term "impact" is used to describe a particular sensory experience, that is defined as the split-second catch that you feel at the back of the throat when you inhale cigarette smoke.

Q. Did you believe that involved the absorption of smoke in the lungs or an effect on the central nervous system?

A. No. As Brown & Williamson used the term, impact is only a local effect in the throat, occurring literally within a split second, before the smoke even gets to the lungs.

Q. The Leaf Blender's Handbook at page 1 mentions that ammonia "can liberate free nicotine from the blend." Was it your view at Brown & Williamson that ammonia could liberate free nicotine?

A. No. Much of the language in the Leaf Blender's Handbook is based upon existing "folklore" that was theorized but not rigorously tested. In particular, some people theorized that ammonia could increase pH and release free nicotine, affecting the taste properties of smoke. In reality, this theory was not borne out by actual research, which showed no increase in pH from the addition of ammonia.

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Q. Was ammonia added, as Dr. Wigand suggests, with the intent to manipulate nicotine levels, either by changing pH or through some other mechanism?

A. No. Such theoretical manipulation was not even possible, and I know of no attempt or intent to use ammonia to "manipulate" nicotine properties.

Q. Dr. Appleton, please look at Exhibit JD-013004, which is the transcript of a secret interview conducted by the FDA of a Brown & Williamson employee, called Macon, in 1994. Have you looked at that document?

A. Yes.

Q. At lines 12-15 on page 54, Macon is asked about whether Brown & Williamson blends its products for tar, rather than nicotine. Her answer is that it is "pretty accurate" to say that "we don't blend for nicotine, we only blend for tar. The nicotine level just falls out where it may." Do you agree or disagree?

A. I agree. Brown & Williamson did not design its tobacco blends or cigarettes with the intent to achieve a certain nicotine level.

Q. In this case, Dr. Kessler testified that when he was at the FDA, the FDA never found that any brand of cigarettes designed and developed by Brown & Williamson was designed with a specific nicotine target. (9/23/04 Kessler Trial Testimony at pp. 581-582). Do you agree or disagree?

A. I agree. Brown & Williamson did not design its cigarettes with the intent to achieve a certain nicotine level.

V. RELATIONSHIP WITH LAWYERS

A. HIRING/ORIENTATION

Q. When you first started at Brown & Williamson, where did you work?

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A. In the law department.

Q. Why was that?

A. I used to work for R.J. Reynolds. When I left R. J. Reynolds, I was subject to a 2 year "non-compete" agreement. I then went to work for Fries and Fries, which did not raise any "non-compete" issues, but when I went to work for Brown & Williamson in 1991 there were still a few months left on my "non-compete" agreement. R.J. Reynolds would not release me from the agreement during those remaining months, but agreed to let me work for Brown & Williamson outside of the R&D department. As a result, for a period of several months I was not permitted to work directly with Brown & Williamson research staff on any substantive work, and so I was assigned an office in the law department.

Q. What type of work did you do in the law department?

A. I was on a self-direct work program. I would basically ask to see certain documents and research reports on certain topics and they were made available to me. I spent a significant portion of my first few months reviewing Brown & Williamson and Southampton research as well as other internal and external research. I particularly used it as an opportunity to familiarize myself with Brown & Williamson and BATCo's past research on smoking and health, additives, and other issues that related to my employment.

Q. Please look at U.S Ex. 79,219. Do you recognize this document?

A. Yes, I do. It is a May 2, 1991 file note from Kendrick Wells.

Q. Do you see where the memo states that Mr. Wells discussed with "Jeff" how you would be "managed" and suggests that Mr. Wells work "closely" with you?

A. Yes.

Q. Who is "Jeff"?

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A. Jeff Wigand.

Q. While stationed at the law department what, if any, role did Kendrick Wells have in your work?

A. I generally kept him informed of what I was doing, but my contact with him was loose. If I needed something, I went to him.

Q. Why did you inform Kendrick Wells of your work?

A. He was my primary contact until I was allowed to work directly with the Research and Development staff. He never substantively reviewed the work I was doing or dictated the work I should do.

Q. After your non-compete agreement expired, did you move offices?

A. Yes. I moved to the R&D building on the other side of town.

Q. After you moved your office to the R&D facility, who became your primary contact point?

A. Jeff Wigand.

Q. When you were hired, did you receive any type of orientation?

A. Yes. I went through a corporate orientation. When I arrived I was walked through different areas of the company, went to different cities where there were operations, such as cigarette manufacturing and smokeless tobacco manufacturing. I also received an overview on the litigation activity.

Q. Were you ever sent to Shook, Hardy and Bacon?

A. Yes.

Q. Do you know why?

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A. Yes. As a part of my orientation, they informed me of the company's ongoing smoking and health litigation, and discussed some of the issues that arise in litigation.

Q. What was your reaction to learning that you were meeting with lawyers as part of your orientation?

A. It seemed appropriate to me. The company was often in litigation.

Q. During your session at Shook, Hardy and Bacon, or at any time, did any lawyers or anyone else ever try to restrict your access to any documents?

A. No.

Q. Were you ever instructed not to make certain statements or types of statements about smoking and health?

A. No.

Q. Do you know what the additives advisory group or panel is?

A. Yes.

Q. Please tell the Court what it is.

A. There were two panels, one at Brown & Williamson and one at BATCo. In both instances, they were a group of scientists within the company whose function was to review the acceptability of proposed new ingredients in cigarettes.

Q. Dr. Wigand alleges that he wanted you to have full control over the additives panel, but that you never did during his tenure. (Wigand Written Direct at 76.) Is that true?

A. I never understood that Dr. Wigand wanted me to do this. Regardless, I began working with both additives panels shortly after the time I left the law department and went to R&D.

Q. Did Kendrick Wells have the authority to veto decisions of the additives panel?

A. Not to my knowledge.

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Q. Did he or any other lawyer for the company ever attempt to veto decisions of the additives advisory panel?

A. Not that I am aware of.

Q. Please look at U.S. Ex. 28,116. Have you seen this document before?

A. Yes, in litigation and preparing for litigation while I was at Brown & Williamson.

Q. Can you please describe this memo for the court?

A. Yes. It is a memo from Kendrick Wells to Bob Northrip and Gordon Smith, two lawyers, commenting on my role at the company in November 1993.

Q. Do you see where he asks whether your [Scott Appleton's] "current practice regarding information about scientific developments was adequate"?

A. Yes.

Q. This memo then raises a number of other questions with respect to you, including whether you should attend scientific conferences normally attended by toxicologists, whether it would be helpful for you to talk with scientists outside the company, and whether routine communication should be occurring between Mr. Sandefur and his advisors. Do you see that?

A. Yes.

Q. What, if any, changes in your job responsibilities or work routine occurred after the date of this memo?

A. There was no change. Nobody ever came to talk with me following this memo. I was never suddenly put into meetings with Mr. Sandefur. I was never asked to attend certain conferences or not attend other conferences, and my contact with outside scientists was not restricted. In fact, the only time I specifically recall speaking with Mr. Sandefur with respect to

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smoking and health issues was in reference to the Waxman hearings, and that was part of a large group of other people.

Q. Did you have discussions at Brown & Williamson about whether you should attend conferences generally attended by toxicologists?

A. Yes. I had discussions with Jeff Wigand about what type of conferences it would make sense to attend based on which were the major or important conferences. At the time, however, I was already attending conferences. I think I have attended every Society of Toxicology meeting there has been except for maybe two or three for the last 15 or 20 years.

B. ALLEGED SUPPRESSION OF RESEARCH

Q. Dr. Appleton, Dr. Wigand has alleged that Brown & Williamson terminated or suppressed certain research into a potentially less hazardous cigarette. Are you familiar with those claims?

A. Yes.

Q. Let's start with Project Rio. What was Project Rio?

A. In Project Rio, BATCo conducted the Ames test on a number of commercial cigarettes to try to discover what design features seem to correlate with either increased or decreased biological activity, with the intent of identifying those features and designing a cigarette that would ultimately reduce biologic activity.

Q. During your time working as a toxicologist at R. J. Reynolds and Brown & Williamson, did you become familiar with Ames testing?

A. Yes.

Q. What is Ames testing?

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A. The Ames test is an *in vitro* test. It is a test conducted in bacteria to measure the mutagenic effects of a substance. In other words, it tests whether a chemical substance is able to cause mutations in bacteria under the conditions of that test. This is based on the theory that cancer is developed from mutated cells.

Q. Was Ames testing developed by the tobacco industry?

A. No. It was developed at a university by an investigator named Bruce Ames.

Q. Do you know if Ames tests were used in the course of doing research into modifying cigarettes by the cigarette industry?

A. Yes, they were.

Q. When you came to Brown & Williamson, did you learn whether Brown & Williamson had done Ames testing?

A. When I started at Brown & Williamson, I familiarized myself with the Ames testing done at BATCo. BATCo did Ames testing and shared that research with Brown & Williamson.

Q. The Court has been shown U.S. Ex. 52,687. Are you familiar with this document?

A. Yes.

Q. For the record, is this a June 12, 1984 file note for from Kendrick Wells?

A. Yes.

Q. What is the subject of this memo?

A. It deals with the legal implications for BAT research and the possible legal implications for Project Rio.

Q. Do you see at the bottom of the middle paragraph where it indicates the need for "direct lawyer involvement" in Project Rio? Did that occur?

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A. Not to my understanding. Work that was part of Project Rio was completed and reports were written. I know of no attempt to interfere with the research.

Q. How do you know that?

A. I am familiar with Project Rio for two reasons. First, during my time at Brown & Williamson the Group Research Center was still engaged in Ames testing. Accordingly, I reviewed the past research on the topic, including project Rio. I also spoke with Ian Massey about Ames testing generally, and Project Rio in particular. Second, as part of preparation to be a witness in litigation in various cases over the years, I have investigated what became of Project Rio by reviewing critical documents and speaking with Ian Massey.

Q. Showing you JD-011372, JD-011666, and JD-011667, are these the research reports resulting from the Ames testing that was part of Project Rio?

A. Yes.

Q. Are these some of the Project Rio reports to which you just testified?

A. Yes.

Q. Do you know whether prior to Project Rio either the Surgeon General or BATCo scientists expressed views on the ability of the Ames test to detect the cancer potential in cigarettes?

A. Yes, they both did.

Q. I would like to show you page 37 of the 1981 Surgeon General's Report, which is marked as JD-000636. Would you please tell the Court what the Surgeon General says about Ames testing?

A. The Surgeon General says,

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"A number of fractions of cigarette smoke condensate are positive in the Ames assay system (93, 101). The agents responsible for this activity have not been fully identified, but probably include products of protein pyrolysis (119). Ames test activity, however, does not predict the activity of fractions in the mouse skin carcinogenesis assay. Fractions of smoke condensate that show activity as complete carcinogens (89) or in a promotion assay that would detect skin carcinogens as well as tumor promoters (24) are not correspondingly active in the Ames system (Table 4). It cannot be determined whether the unidentified mutagens in cigarette smoke are an important cause of lung cancer in humans; however, added exposure to any tumor initiators probably carries an incremental risk of cancer."

Q. Showing you JD-011374, please identify this for the Court.

A. It is a BATCo research report regarding mutagenic activity and the Ames test.

Q. Is this report consistent with the 1981 Surgeon General's report?

A. Yes. On page 2, the document explains that Ames testing is not an infallible guide to cancer potential, although it is viewed by some advisory regulatory bodies as being an early warning that further testing is required. It further is clear from page 30, that the Ames testing cannot be used to set safe levels of exposure in man.

Q. Was this view shared by Brown & Williamson during your time at the Company?

A. Yes.

Q. In light of the Surgeon General's position and BATCo's position in 1982, do you know why Project Rio was conducted?

A. Yes. Nobody knew what component of smoke caused disease. Recognizing the limitations of Ames testing, many scientists thought there was some relationship between mutagenic activity and carcinogenic activity. In addition, it was anticipated that regulators might require Ames testing on cigarettes. Finally, regardless of its ability to predict carcinogenesis, Ames testing was useful for analyzing the effects of new additives in cigarettes.

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Q. To your knowledge, since Project Rio, has Ames testing yielded definitive data regarding the relationship between cigarette design and human disease?

A. No, it has not.

Q. Next, I would like to turn to some allegations in this case about other safer cigarette research. Are you familiar with Project Airbus?

A. Yes.

Q. What was Project Airbus?

A. Project Airbus was Brown & Williamson's attempt to develop a cigarette that was heated, not burned, similar to Premier.

Q. Dr. Wigand has alleged that after the September, 1989 Vancouver conference, Project Airbus was terminated. Is that true?

A. No. Airbus was terminated at Brown & Williamson in March 1989.

Q. Dr. Wigand also claims that project Airbus was stopped by Thomas Sandefur because of litigation concerns. Is that true?

A. No.

Q. Why was it terminated?

A. What happened was that Airbus was taken to a certain point and basically the Company ran into all kinds of technical problems. The bottom line was that Brown & Williamson could not get it to work. More fundamental work was needed. Given that, the project was terminated at Brown & Williamson, but related work was continued in Southampton, as it specialized in the type of fundamental research that needed to be conducted. That, the Company hoped, would push the project forward.

Q. How do you know that to be the case?

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A. It is well documented in Brown & Williamson's files. As part of my review of past Brown & Williamson research work and in preparation for being a witness in litigation over the years I have reviewed the documents surrounding Project Airbus.

Q. Please look at JD-011688. What is this document?

A. It is a March 13, 1989 fax from Alan Head to Jeff Wigand regarding Project Airbus.

Q. Is this consistent with your understanding of what happened to Project Airbus?

A. Yes. It indicates that a decision was made to discontinue Project Airbus work in Louisville and to develop it at Southampton.

Q. Please look at JE-053344. What is this?

A. It is an Airbus review dated March 6, 1989.

Q. What, if anything, does this document indicate were the reasons Project Airbus was terminated?

A. It indicates that Brown & Williamson could not get the product to work because of technical problems, such as overheating. Further, Premier had been recalled because of deficiencies in taste, aroma and smoking mechanics. It also indicates that fundamental research related to this project would continue at Southampton.

Q. What happened after the project was terminated?

A. Related research began in Southampton.

Q. What, if any, other safer cigarette projects were conducted by Brown & Williamson after the 1989 Vancouver Conference?

A. Since 1989, Brown & Williamson has conducted research into a wide range of strategies and technologies for reducing toxins in cigarette smoke. Some of the projects included Project Trump, parts of Project Day, and the work on Advance. These and other similar projects cost

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substantial amounts of money and manpower. Additional work was also done as part of the group research program with BATCo.

Q. What is Advance?

A. It is an attempt at making a conventional cigarette reduced in a variety of toxins, such as TSNAs, that are believed to play a role in smoking related diseases. It was introduced in test markets before I left Brown & Williamson.

C. ALLEGED DOCUMENT EDITING

Q. There have been claims in this case that lawyers at Brown & Williamson edited research reports. Specifically, Jeffrey Wigand claims that Kendrick Wells would review and edit scientific research from BATCo, sometimes before the Brown & Williamson scientists ever saw it. In your time at Brown & Williamson, did any lawyer ask or demand to edit any of your research reports?

A. No, I do not recall that happening to me. I do remember on one occasion when Kendrick Wells asked me if I wanted a lawyer to review a position paper I was doing on pyrolysis. I thought it was a good idea.

Q. Why did you agree to have a lawyer review the paper?

A. Mainly, I wanted to make sure that nothing was ambiguous. I also wanted to make certain that it was consistent with the current regulatory and legal standards. He made some suggestions, and that was the end of it. I did not incorporate any suggestions I did not agree with.

Q. Do you recall any other time when lawyers edited any of your work product?

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A. The only other time I recall was I prepared preliminary drafts of the web site statements. I believe lawyers were included in the process but I do not know who or the extent of their involvement.

Q. Did you ever publish any research paper while at Brown & Williamson?

A. Yes.

Q. Were you required to have a lawyer review the paper prior to publication?

A. No.

VI. DOCUMENT PRESERVATION

Q. Let's turn to some claims regarding alleged document destruction. When you came to Brown & Williamson, what was the policy with respect to the retention of research and development documents?

A. All documents were under a hold or no destruction order.

Q. Did this include documents received from Southampton and other BATCo research facilities?

A. Yes.

Q. Please look at JD-011288. Is this and example of a hold order during your time at Brown & Williamson?

A. Yes.

Q. Do you know how long R&D documents, including those received from BATCo, have been on permanent hold at Brown & Williamson.

A. At least since the early 1980s, and possible the 1970s.

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Q. In response to allegations regarding the routing and destruction of BATCo documents by Brown & Williamson, did Brown & Williamson ever engage in a document audit of BATCo documents in Brown & Williamson's files?

A. Yes.

Q. Who conducted the audit?

A. Hugh Honeycutt did with the assistance of many others.

Q. Do you have firsthand knowledge of the actual process by which the audit took place?

A. Yes.

Q. Have you testified about this audit in the past?

A. Yes. I testified about the audit in the *Falise* case in 2000.

Q. Would you please describe the audit process to the court?

A. The audit was an attempt to confirm that Brown & Williamson received all of the BATCo R&D documents it was supposed to receive. The first step was we received from BATCo's Southampton research facility a list of reports that were issued to Brown & Williamson. The R&D scientists then received from the Brown & Williamson library a printout of documents actually received. The R&D scientists then compared the two. If a report was not located, the scientists would check with Southampton to make sure it was actually sent. The scientists also reviewed the boxes of documents in the library basement.

Q. Please look at JD-011613, JD-012750, and JD-011385. What are these?

A. These are summary sheets that relate to the results of the audit.

Q. The summary refers to reports with a letter prefix. Can you tell the Court what those letters stand for?

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A. They are different classifications of reports: "RD," "T," "E," "L," and "P." RD were research and development reports.

Q. What did the audit show with respect to RD reports sent to Brown & Williamson from BATCo during the 35 years from 1957-1992?

A. It showed that 94 out of approximately 1900 reports were missing. That is about 5%.

Q. Let's focus on the period from November 1979-1992, during which the Government has alleged Brown & Williamson had various concerns about BATCo research reports. What did the audit show with respect to RD reports from November 1979-1992?

A. It showed that all but 4 of approximately 470 reports are in the R&D library or other regular R&D files. That is approximately 99%. With respect to those 4 reports, there were no similarities in terms of date or subject matter.

Q. What did the audit show with respect to "P" reports from BATCo from 1992-1998?

A. It showed that Brown & Williamson was only missing one out of 114 P reports.

Q. Please look at JD-011345. What is this?

A. This is a list of RD reports not located at Brown & Williamson. It identifies the four missing reports I just testified to.

Q. For any of the reports noted as missing from November 1979-1992, did you detect any similarities?

A. There were no similarities in terms of date or subject matter. As you would imagine, out of thousands of reports received over the years, some slip through the cracks and are missing. We have looked at the ones that are missing, and they do not reflect any particular pattern. They do not have a common subject matter, such as biological activity, smoking and health, or any

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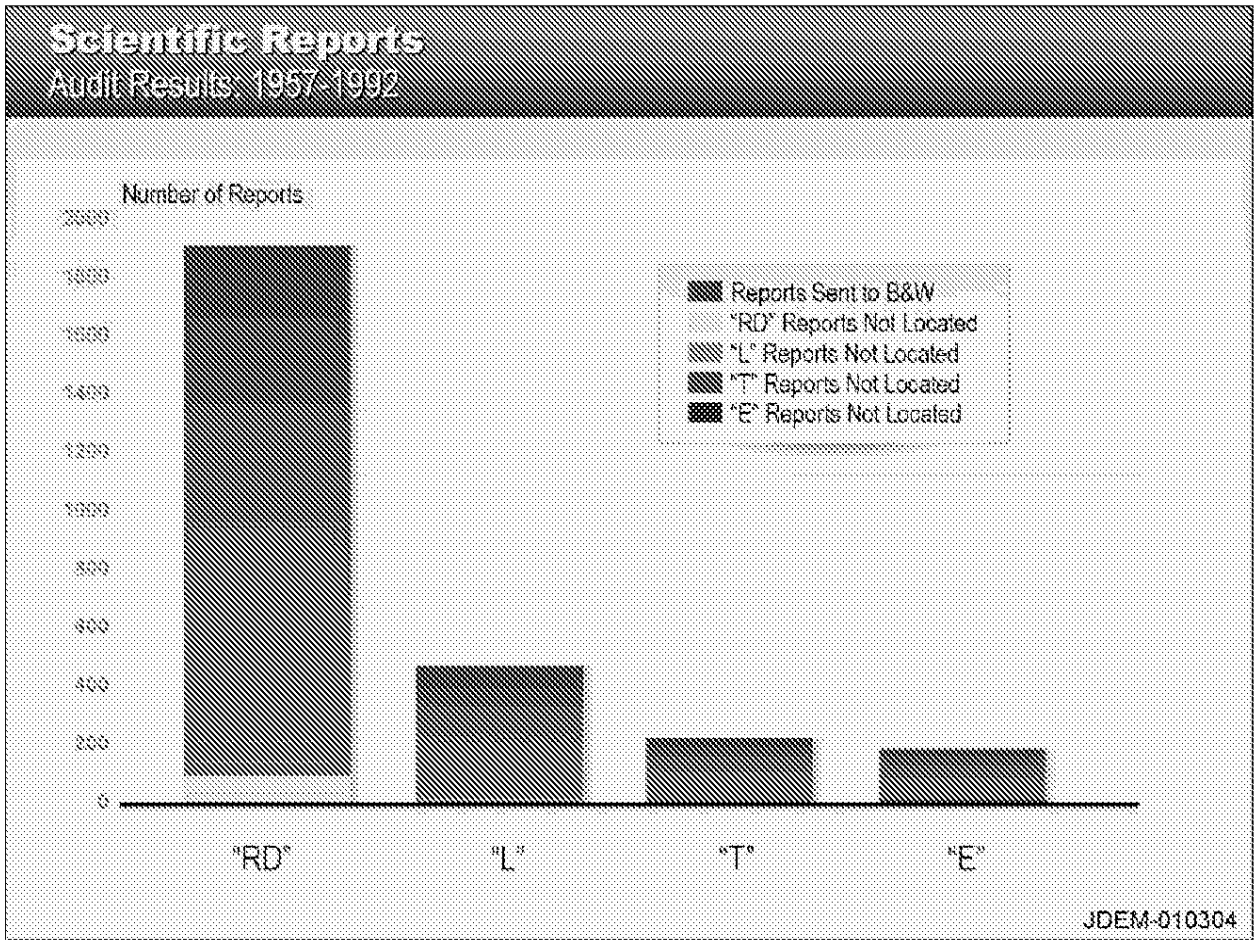
other topic. Moreover, you have to remember that the Brown & Williamson research facility moved twice since the 1950s.

Q. Please look at JDEM-10304, JDEM-010302, and JDEM-010303. What are these?

A. These are graphic depictions of the result of the audits and depict the testimony I just gave. They are consistent with the summary reports we just discussed.



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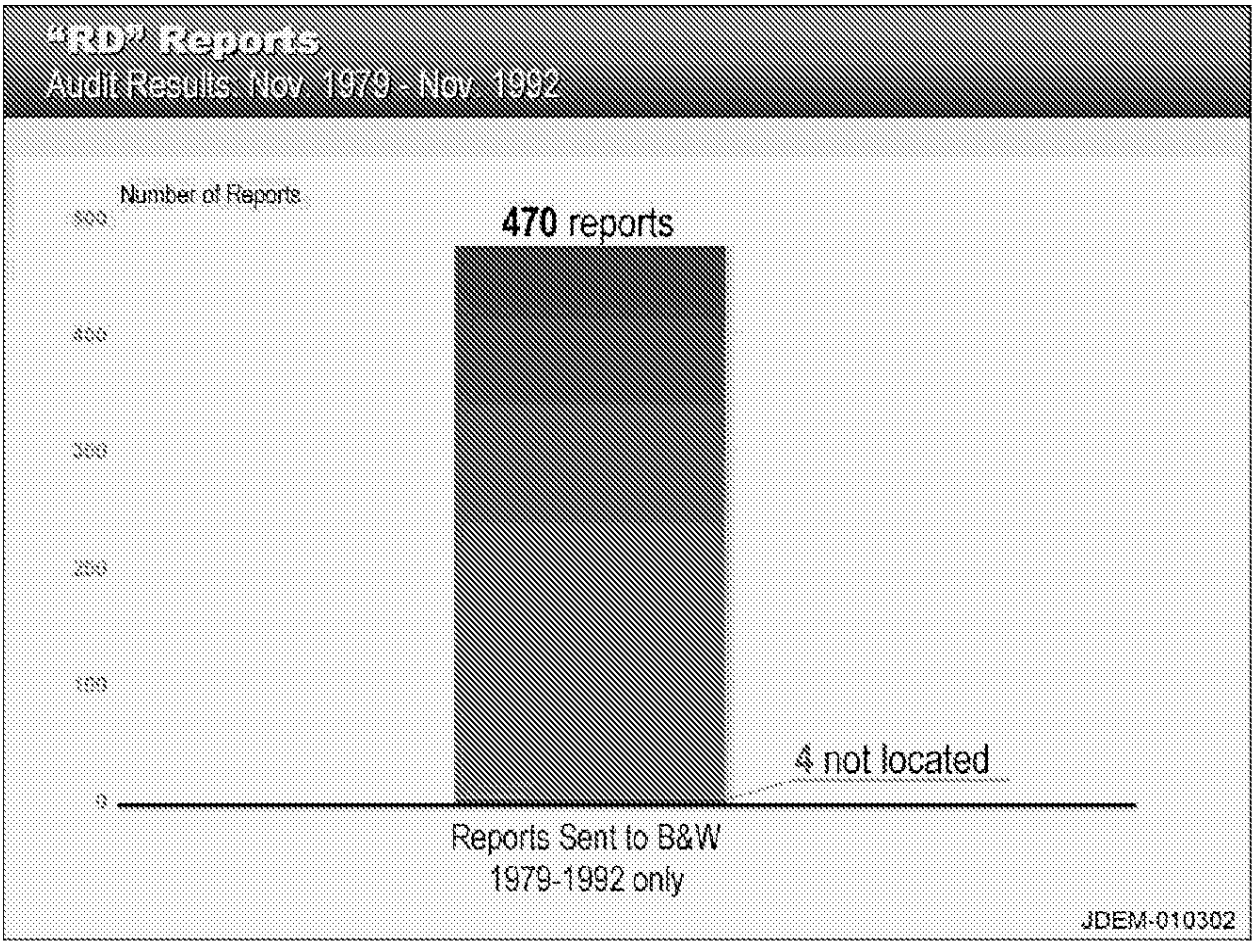

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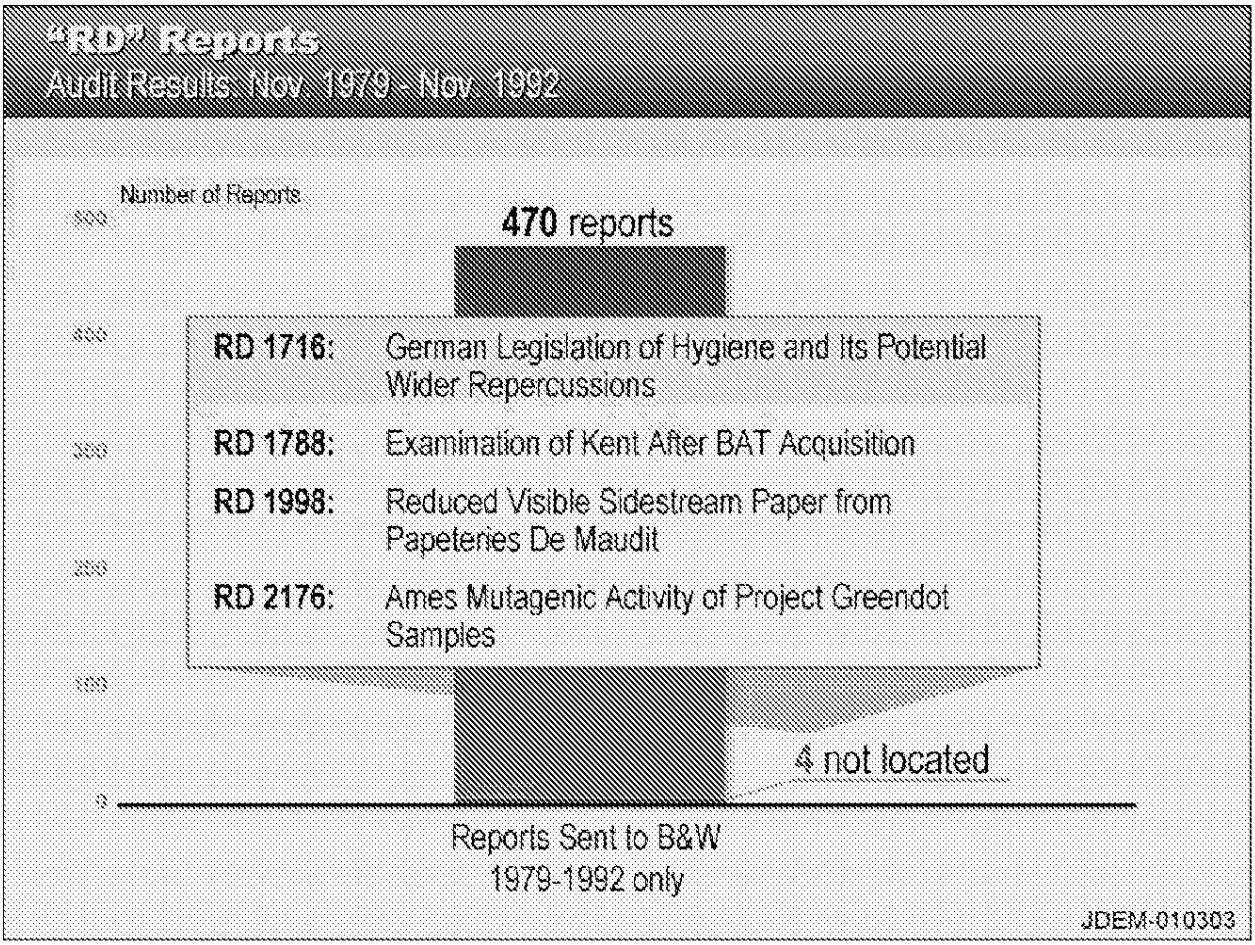

A. JANUS REPORTS

Q. Are you familiar with the Janus Studies?

A. Yes.

Q. What are they?

A. The Janus Studies were reports that related to mouse skin painting and an analysis of biological activity in smoke condensate.

Q. Are you familiar with U.S. Ex. 21,772, a January 17, 1985 memo from Kendrick Wells?

A. Yes. I have seen this document several times in litigation and preparing to testify.

Q. Have you ever heard this referred to as the "Deadwood" memo?

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A. Yes.

Q. As you can see from the language of the document, it discusses segregating and then possibly shipping back to BATCo a number of documents, which are classified as "deadwood," including the Janus reports. Do you know whether these reports were shipped back to BATCo or destroyed?

A. I know that they were not shipped back to BATCo nor were they destroyed.

Q. How did you learn that fact?

A. One of my responsibilities when I first came to Brown & Williamson was managing the library. When the library gave me an orientation briefing they brought to my attention the fact that certain documents were in a separate storage location referred to as a records retention location. I asked to see these documents, so they took me to where the documents were being stored and I flipped through them. I observed a number of Janus reports as well as other reports. The Janus documents were still at Brown & Williamson at the time I left.

B. ADDITIVE TESTING

Q. Let's turn to the issue of additive testing. During the time you were with R.J. Reynolds and then with Brown & Williamson, did you do work with additive testing?

A. Yes.

Q. Please describe the work you did.

A. My work covered an assortment of activities that can be summed up as testing additives currently in cigarettes and the effects of adding new additives to cigarettes.

Q. What, if any, steps did you take to familiarize yourself with the additive testing done at Brown & Williamson?

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A. As this was a central component of my work, I looked closely at the Brown & Williamson records on additive testing, including past testing data and reports and summaries. I also spoke to those who had institutional knowledge.

Q. Please look at U.S. Ex. 30,481. Are you familiar with this document from your time at Brown & Williamson?

A. Yes.

Q. For the record, is this a September 25, 1981 memorandum from Kendrick Wells to Ernest Pepples regarding "Additives"?

A. Yes.

Q. The memo says on page 3 that if "company testing began to show adverse results pertaining to a particular additive, the company control would enable the company to terminate the research, remove the additive, and destroy the data." Did this occur?

A. Certainly not while I was at the company, and I have seen no evidence that it occurred previously.

Thank you Dr. Appleton. No further questions.

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